

Remarks

The April 20, 2006 Office Action raised § 112 concerns. In view of the amendments above, and remarks below, reconsideration is respectfully requested.

Applicants have now canceled (or previously withdrawn) all but claims 1, 2 and 9. Further, even these remaining claims have now been amended to better respond to the specific concerns raised in the latest Office Action. All claims are proposed to:

1. be limited to the disease being kidney transplant rejection;
2. be amended so that the sample is a portion of the transplanted kidney;
3. specify that the marker protein is the phosphorylated or regular SEQ. ID. NO. 1;
4. specify that it is labeled antibody binding that facilitates the analyzing;
5. specify a comparing step which more specifically ties in the other process attributes;
6. specify a detection step.

These changes are believed to address the issues raised in the Office Action as follows:

§ 112 New Matter Issues

The new matter objections related to the term "kidney disease", the term "materials derived therefrom", and references to terms relating to perceiving and visualization. The original abstract made clear that a transplant rejection was to be considered a form of disease state for purposes of this application, and original claim 10 described a kidney as a target transplant organ. Thus, no new matter issue was raised by using this language. In any event, to expedite prosecution, the remaining claims are now focused on kidney transplant rejection.

At various places, including paragraphs [0018] and [0023], there was a description of creating a homogenate from the sample, resulting in fragments which were then analyzed. This is described as an alternative to creating an antibody to the marker protein itself. Thus, there was considerable support in the original specification for certain species with respect to "materials derived". In any event, to expedite prosecution, the remaining claims have now been amended to make clearer that the derived materials are homogenates.

The original application did speak in terms of visualizing. Nevertheless, to expedite matters, the "perceiving" and "visualization" type language has now been replaced by references to labeled antibodies. Thus, all new matter concerns are believed to be addressed.

§ 112 Enablement Issues

The Office has recognized enablement of some subject matter. Working from what the Office appeared to be comfortable with in this regard:

- (a) all remaining claims are limited to the disease being kidney transplant rejection;
- (b) all claims are limited to the sample being a portion of the transplanted kidney;
- (c) all claims now specify that the marker protein in question is the phosphorylated or regular SEQ. ID. NO. 1;
- (d) all claims specify that it is labeled antibody binding that facilitates the analyzing.

While the Office Action acknowledged enablement for an antibody to SEQ. ID. NO. 1 itself, the specification also teaches use of an antibody to a homogenate fragment. Hence, that subject matter remains in the claim as well.

Specific Office Action concerns regarding claims 4 and 7 are now moot as those claims have now been canceled.

As such, all enablement concerns are now believed to be adequately addressed.

§ 112 Written Description Issues

The written description concerns in the Office Action largely mirror those raised in the new matter and/or enablement portions of the Office Action, and for similar reasons are now believed to be adequately addressed.

§ 112 Omission Of Steps Issue

Paragraph 16 of the Office Action appears to be asserting concerns regarding omission of an essential step under § 112. There is a suggestion that a detection step and a correlation step be included. That has now been done. Note also that the antibody is described as the essential ingredient for the contacting step, and the correlation step is described in the context of a comparing step, as requested.

The Office Action also had a specific suggestion regarding including information in the claim about the direction of result and what that would implicate. Hence, a further amendment has been included relating to that. See paragraphs [0033] and [0037] which indicate that absence or reduction in the marker protein presence is indicative of the disease state.

Conclusion

Consideration of this amendment at this time is appropriate as no substantive rejections are pending and nothing herein would require further searching. Also, the above amendments largely track the examiner's suggestions and indications.

No additional fee is believed necessary for the consideration of this amendment. However, if one is, please charge Deposit Account 17-0055 for the needed fees.

Respectfully submitted,

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By: _____

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